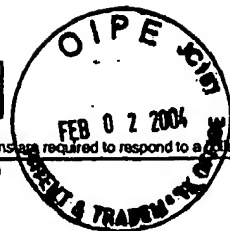


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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/613,975
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Filing Date	July 3, 2003
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First Named Inventor	Donald L. Wise
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Group Art Unit	1642
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Examiner Name

Attorney Docket Number	CSI 130
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Sheet	1	of	8
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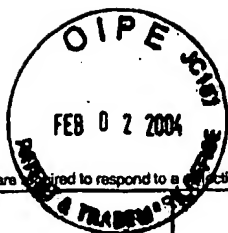
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/613,975
		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
		Examiner Name	
Sheet 2 of 8	Attorney Docket Number	CSI 130	

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KS		ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," <i>Pharm. Res.</i> 10(7): 945-953 (1993).	
		ANCHORDOQUY & KOE, "Physical stability of nonviral plasmid-based therapeutics," <i>J. Pharm. Science.</i> 89(3): 289-296 (2000).	
		ARORA & LEPPLA, "Residues 1-254 of anthrax toxin lethal factor are sufficient to cause cellular uptake of fused polypeptides," <i>J. Biol. Chem.</i> 268: 3334-3341 (1993).	
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		DEHAAN, et al., "The role of ADP-ribosylation and G _{M1} -binding activity in the mucosal immunogenicity and adjuvanticity of the <i>Escherichia coli</i> heat-labile enterotoxin and <i>Vibrio cholerae</i> cholera toxin," <i>Immun. Cell Biol.</i> 76: 270-279 (1998).	
KS		DENNIS, et al., "Tularemia as a biological weapon," <i>JAMA</i> 285(21): 2763-2773 (2001).	

Examiner's Signature		Date Considered	6/14/04
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		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
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Sheet 3 of 8	Attorney Docket Number	CSI 130	

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✓		DOOLAN, et al., "Circumventing genetic restriction of protection against malaria with multigene DNA immunization: CD8 ⁺ T cell-, Interferon γ -, and nitric oxide-dependent immunity," <i>J. Exp. Med.</i> 183: 1739-1746 (1996).	
		DUESBERY, et al., "Proteolytic inactivation of MAP-kinase-kinase by anthrax lethal factor," <i>Science</i> 280: 734-737 (1998).	
		ELDRIDGE, et al., "Biodegradable and biocompatible poly(DL-lactide-co-glycolide) microspheres as an adjuvant for staphylococcal enterotoxin B toxoid which enhances the level of toxin-neutralizing antibodies," <i>Infect. Immunity</i> . 59: 2978-2986 (1991).	
		ELKINS, et al., "Rapid generation of specific protective immunity to <i>Francisella tularensis</i> ," <i>Infect. Immun</i> 60(11): 4571-4577 (1992).	
		ELKINS, et al., "Bacterial DNA containing CpG motifs stimulates lymphocyte-dependent protection of mice against lethal infection with intracellular bacteria," <i>J. Immunol.</i> 162(4): 2291-2298 (1999).	
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		GARDNER, et al., "Chromosome 2 sequence of the human malaria parasite <i>Plasmodium falciparum</i> ," <i>Science</i> 282: 1126-1132 (1998).	
✓		GILLEY, et al., "Microencapsulation and its application to vaccine development," <i>Proc. 19th Int. Symp. Control. Rel. Bioact. Mater.</i> 19: 110-111 (1992).	

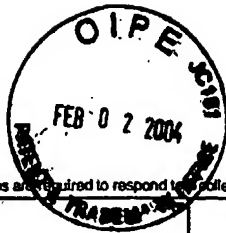
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		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
		Examiner Name	
Sheet 4 of 8	Attorney Docket Number	CSI 130	

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km		GORDON, et al., "Proteolytic activation of bacterial toxins by eukaryotic cells is performed by furin and by additional cellular proteases," <i>Infect. Immun</i> 63: 82-87 (1995).	
		GU, et al., "Protection against anthrax toxin by vaccination with a DNA plasmid encoding anthrax protective antigen," <i>Vaccine</i> 17: 340-344 (1999).	
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		GUY, et al., "Effects of the nature of adjuvant and site of parenteral immunization on the serum and mucosal immune responses induced by a nasal boost with a vaccine alone," <i>Clin. Diagn. Lab. Immunol.</i> 5(5): 732-736 (1998).	
		GUY, et al., "Systemic immunization with urease protects mice against <i>Helicobacter pylori</i> infection," <i>Vaccine</i> 16(8): 850-856 (1998).	
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		HOFFMAN, et al., "Toward clinical trials of DNA vaccines against malaria," <i>Immun. Cell Biol.</i> 75: 376-381 (1997).	
		HSU, et al., "Effect of polymer foam morphology and density on kinetics of <i>in vitro</i> controlled release of isoniazid from compressed foam matrices," <i>J. Biomed. Mat. Res.</i> 35: 107-116 (1997).	
		IVINS, et al., "Recent advances in the development of an improved human anthrax vaccine," <i>Eur. J. Epidemiol.</i> 4: 12-19 (1988).	
		KAWABATA, et al., "The fate of plasmid DNA after intravenous injection in mice: involvement of scavenger receptors in its hepatic uptake," <i>Pharm. Res.</i> 12(6): 825-830 (1995).	

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Application Number	10/613,975
Filing Date	July 3, 2003
First Named Inventor	Donald L. Wise
Group Art Unit	1642
Examiner Name	
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Sheet 5 of 8

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ICM		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci., USA</i> 89: 10277-10281 (1992).	
		KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," <i>Infect. Immunol.</i> 67: 5658-5663 (1999).	
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		LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in <u>Bacterial protein toxins</u> (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).	
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		LITTLE & KNUDSON, "Comparative efficacy of <i>Bacillus anthracis</i> live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," <i>Infect. Immun.</i> 52(2): 509-512 (1986).	

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		Group Art Unit	1642
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Sheet 6 of 8	Attorney Docket Number	CSI 130	

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✓		LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
		LUO, et al., "Synthetic DNA delivery systems," <i>Nature Biotech</i> 18: 33-37 (2000).	
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		O'HAGAN, et al., "Controlled release microparticles for vaccine development," <i>Vaccine</i> 9: 768-771 (1991).	
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		PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," <i>J. Imm. Meth.</i> 195: 135-138 (1996).	
✓		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," <i>J. Control. Rel.</i> 75: 211-224 (2001).	

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✓		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," <i>Vaccine</i> 13(15): 1427-1430 (1995).	
		PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infect. Immunity</i> 69(7): 4509-4515 (2001).	
		SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," <i>Proc. Nat. Acad. Sci. USA</i> 95: 7648-7653 (1998).	
		SEDEGAH, et al., "Improving protective immunity induced by DNA-based immunization: priming with antigen and GM-CSF-encoding plasmid DNA and boosting with antigen-expressing recombinant poxvirus," <i>J. Immun.</i> 164: 5905-5912 (2000).	
		SINGH, et al., "Controlled delivery of diphtheria toxoid using biodegradable poly(D,L-lactide) microcapsules," <i>Pharm. Res.</i> 8: 958-961 (1991).	
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		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium falciparum</i> malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
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		TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," <i>J. Control. Rel.</i> 66: 229-241 (2000).	
✓		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," <i>Proc. 5th World Congress, Chem. Eng.</i> (1996).	

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		First Named Inventor	Donald L. Wise		
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W		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mat. Res.</i> 19: 349-365 (1985).	
		WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four <i>Plasmodium falciparum</i> DNA plasmids," <i>Infect. Immunity</i> 66(9): 4193-4202 (1998).	
		WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
		WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," <i>Science</i> 247: 1465-1468 (1990).	
		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," <i>Immunol. Res.</i> 16(2): 187-201 (1997).	
W		YEE, et al., "Loss of either CD4 ⁺ or CD8 ⁺ cells does not affect the magnitude of protective immunity to an intracellular pathogen, <i>Fancisella tularensis</i> strain LVS," <i>J. Immunol.</i> 157: 5042-5048 (1996).	

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